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|-------------------------------|------------------------|---------------------|--|
| Notice of Allowability | Application No. | Applicant(s) | |
| | 09/821,571 | MCCAFFREY ET AL. | |
| | Examiner | Art Unit | |
| | Gordon J. Stock | 2877 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment filed 1/24/05.
2. ☒ The allowed claim(s) is/are 1-62.
3. ☒ The drawings filed on 02 August 2004 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☒ to Paper No./Mail Date 9/16/03 (#7).
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____ 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6. <input type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date _____ 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input checked="" type="checkbox"/> Other <u>PTOL-413B</u>. |
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EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Attorney Ian McLeod on March 1, 2005. Please see attached PTOL-413B.

Amendment made to clarify terms ITO, L1, and L2 in the claims and to overcome possible objections due to lack of antecedent basis with the term "other entity capable of generating chemiluminescence," "other entity capable of chemically reacting to generate chemiluminescence" and other limitations.

Amended claims are:

1. (Currently amended) A hand-held assay device for measuring the presence of a sample ~~selected from the group consisting of ATP and other entity capable of generating~~ chemiluminescence, comprising:

a housing with a closeable door for enclosing the sample in a sample compartment of the housing so that the sample is inside the housing in the absence of a source of light from outside of the housing when the door is closed;

a first light sensor inside the housing for generating a sample signal in response to detecting the chemiluminescence;

a second light sensor inside the housing shielded from the chemiluminescence and generating a reference signal;

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a controller inside the housing receiving the sample signal and the reference signal, wherein the controller outputs a resulting signal indicative of the sample and determined as the difference between the sample and reference signals; and

software executed on the controller for determining the presence of light from outside the housing when the door is open and for generating a warning signal in response to the detection of the light, wherein the controller prevents the device from operating further unless there is an absence of a source of light from outside of the housing.

6. (Currently amended) A hand-held assay device for measuring the presence of a sample ~~selected from the group consisting of ATP and other entity capable of generating chemiluminescence~~, comprising:

a housing for enclosing ~~[[a]]~~ the sample in a sample compartment so that the sample is inside the housing in the absence of a source of light from outside of the housing;

a first light sensor inside the housing for generating a sample signal in response to detecting the chemiluminescence;

a second light sensor inside the housing shielded from the chemiluminescence and generating a reference signal;

a controller inside the housing receiving the sample and reference signal to output a resulting signal indicative of the sample and determined as the difference between the sample and reference signals, wherein the controller is a microprocessor having a memory which stores a sample threshold value;

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software executing on the microprocessor for closing [[the]] solid state switches for initiation of a controllable integration time to provide the integrated values of the sample and reference signals corresponding to the duration of the closed state of the solid state switches;

software for comparing a value representing the resulting signal to the sample threshold value to determine if the resulting signal is at least equal to the sample threshold value;

software executed on the controller for incrementally increasing the integration time if the resulting signal is less than the sample threshold value;

software executed on the controller for completing the determination of the sample upon reaching a predetermined integration time limit stored in the memory; and

software executed on the controller for detecting negative saturation of a switched integrator due to a rapid environmental change and for setting an integration time limit shorter than the predetermined time limit.

9. (Currently amended) A hand-held assay device for measuring the presence of a sample ~~selected from the group consisting of ATP and other entity capable of generating chemiluminescence~~, comprising:

a housing for enclosing the sample in a sample compartment so that the sample is inside the housing in the absence of a source of light from outside of the housing;

a first light sensor inside the housing for generating a sample signal in response to detecting the chemiluminescence;

a second light sensor inside the housing shielded from the chemiluminescence and generating a reference signal;

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a controller inside the housing receiving the sample and reference signal to output a resulting signal indicative of the sample and determined as the difference between the sample and reference signals;

an LED turned on in response to powering up the device to emit a beam of light extending along a path; and

a transparent window along the path between the LED and the first light sensor, the controller having a calibration mode, wherein the cleanliness of the window is controlled in response to a signal generated by the first light sensor which struck by the beam from the LED.

13. (Currently amended) A hand-held assay device for measuring the presence of a sample ~~selected from the group consisting of ATP and other entity capable of~~ generating chemiluminescence, comprising:

a housing for enclosing the sample in a sample compartment so that the sample is inside the housing in the absence of a source of light from outside of the housing;

a first light sensor inside the housing for generating a sample signal in response to detecting the chemiluminescence;

a second light sensor inside the housing shielded from the chemiluminescence and generating a reference signal;

a controller inside the housing receiving the sample and reference signal to output a resulting signal indicative of the sample and determined as the difference between the sample and reference signals; and

a transparent window in the sample compartment upstream from the first light sensor and a door spaced from the transparent window wherein a LED is mounted in a

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peripheral wall of the sample compartment and spaced from the transparent window, wherein a consumable for generating the chemiluminescence in the presence of the sample, which has been used to swab a surface to collect the sample to be tested, is removably inserted into the sample compartment to bring the sample to the window.

17. (Currently amended) The hand-held assay device defined in Claim 15, further comprising software executed on the controller for turning a LED off if the value of the signal inputted in the controller has been determined to be at least equal to the mid-level but less than the high level of the predetermined range with the LED on, wherein the mid-level corresponds to a stored LED reference value, software executed on the controller for determining a new integrated value of the signal detected in response to turning the LED off, and software executed on the controller for comparing the integrated values L1, the difference between the sample signal and the reference signal, and L2, a resulting consumable signal, with the LED on and the LED off, respectively, to display the signal indicative of the presence of the consumable if these integrated values are substantially the same.

25. (Currently amended) The hand-held assay device defined in claim 24 wherein the coating is indium tin-oxide, ~~[[ITO]]~~ ITO, placed on the side of the window, which faces away from a first photodiode, to form with a chassis of the hand-held device a discharging element acting as a Faraday cage, the opposite side of the window being covered with a filter to limit the light striking the first photodiode.

26. (Currently amended) The hand-held assay device defined in claim 23 wherein the window is made from a ~~colored~~ coated glass to serve as a filter selected from the

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group consisting of a band pass filter[[,]] and band-limited filter ~~and combination of these.~~

28. (Currently amended) A hand-held assay device for measuring the presence of a sample ~~selected from the group consisting of ATP and other entity capable of~~ generating chemiluminescence, comprising:

a housing for enclosing the sample in a sample compartment so that the sample is inside the housing in the absence of a source of light from outside of the housing;

a chassis within the housing comprising a conductive material;

a first light sensor inside the housing for generating a sample signal in response to detecting the chemiluminescence;

a second light sensor inside the housing shielded from the chemiluminescence and generating a reference signal;

a controller inside the housing receiving the sample and reference signal to output a resulting signal indicative of the sample and determined as the difference between the sample and reference signals;

a transparent window in the sample compartment, covered with an electro-conductive coating ~~plastic~~ in electrical contact with the chassis, and having a filter which is a bandpass filter or a band-limited filter upstream from the first light sensor and a door spaced from the window; and

an optic including a pair of plano-convex lens opposedly oriented between ~~[[the]]~~ a consumable and the transparent window to focus and then spread the light, wherein in use ~~the~~ the ~~[[a]]~~ consumable comprising ~~[[the]]~~ an entity on a swab for generating the chemiluminescence in the presence of the sample has been used to swab a surface to

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collect the sample to be tested, is inserted through the door into the sample compartment to bring the sample towards the transparent window, and wherein the transparent window is spaced from the bottom of the consumable.

29. (Currently amended) A hand-held assay device for measuring the presence of a sample ~~selected from the group consisting of ATP and other entity capable of~~ generating chemiluminescence, comprising:

- a housing for enclosing the sample in a sample compartment so that the sample is inside the housing in the absence of a source of light from outside of the housing;

- a first light sensor inside the housing for generating a sample signal in response to detecting the chemiluminescence;

- a second light sensor inside the housing shielded from the chemiluminescence and generating a reference signal;

- a controller inside the housing receiving the sample and reference signal to output a resulting signal indicative of the sample and determined as the difference between the sample and reference signals;

- a transparent window in the sample compartment upstream from the first light sensor and a door spaced from the window; and

- software executed on the controller for determining the presence of an opening in the door and for generating a warning signal in response to the detection of the light from the opening;

- wherein ~~[[the]]~~ an entity on a swab in a consumable for generating the chemiluminescence in the presence of the sample has been used to swab a surface to

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collect the sample to be tested and inserted through the door into the sample compartment to bring the sample towards the window.

30. (Currently amended) A hand-held assay device for detecting the presence of a sample ~~selected from the group consisting of ATP and other entity capable of chemically reacting to generate~~ generating chemiluminescence, comprising:

a housing with a closeable door for enclosing a removeable consumable containing the sample in a sample compartment of the housing so that the sample and the consumable are inside the housing in absence of a source of light from outside of the housing when the door is closed;

a detection assembly inside the housing for detecting the chemiluminescence in the sample compartment from the consumable and generating a sample signal in response to its detection;

a transparent window inside the housing between the sample compartment and detection assembly, said transparent window being covered with a conductive transparent coating to minimize the direct injection of static charge from the consumable;

a light source in the sample compartment which when activated emits light which projects through the transparent window and strikes the detection assembly to generate a reference signal; and

a controller inside the housing and software executed on the controller for comparing the reference signal to a reference value so as to prevent the device from operating further unless the reference signal is below a threshold suggesting that light from outside of the housing is absent, and when the light source is turned off for

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determining whether a resulting signal processed in response to the sample signal generated by the detection assembly is indicative of the presence of the sample.

32. (Currently amended) The hand-held assay device defined in claim 30 wherein the transparent conductive coating on the window is indium tin-oxide, ITO ~~[[ITO]]~~.

34. (Currently amended) A hand-held assay device for detecting the presence of a sample ~~selected from the group consisting of ATP and other entity capable of chemically reacting to generate~~ generating chemiluminescence, comprising:

a housing provided with a sample compartment for enclosing the sample so as to generate the chemiluminescence in the sample compartment so that the sample is inside the housing in absence of a source of a light from outside of the housing;

a detection assembly inside the housing for detecting the chemiluminescence and generating a signal in response to its detection;

a transparent window inside the housing between a sample chamber and detection assembly, said transparent window being covered with a conductive transparent coating to minimize the direct injection of static charge and wherein the transparent window has opposite sides, one of which is coated with indium tin oxide, ~~[[an]]~~ ITO, providing a shutterless structure of the hand-held device, whereas the other side of the transparent window has a bandpass filter selected from the group of a coating and a whole body; and

a controller inside the housing for determining whether a resulting signal processed in response to the signal generated by the detection assembly is indicative of the presence of the sample.

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35. (Currently amended) A hand-held assay device for detecting the presence of a sample ~~selected from the group consisting of ATP and other entity capable of chemically reacting to generate~~ generating chemiluminescence, comprising:

a housing provided with a sample compartment for enclosing the sample so as to generate the chemiluminescence in the sample compartment so that the sample is inside the housing in absence of a source of a light from outside of the housing;

a detection assembly inside the housing for detecting the chemiluminescence and generating a signal in response to its detection;

a transparent window inside the housing between a sample chamber and detection assembly, said transparent window being covered with a conductive transparent coating to minimize the direct injection of static charge, wherein a first photodiode is juxtaposed with the side of the transparent window provided with a bandpass filter; and

a controller inside the housing for determining whether a resulting signal processed in response to the signal generated by the detection assembly is indicative of the presence of the sample.

36. (Currently amended) A hand-held assay device for detecting the presence of a sample ~~selected from the group consisting of ATP and other entity capable of chemically reacting to generate~~ generating chemiluminescence, comprising:

a housing provided with a sample compartment for enclosing the sample so as to generate the chemiluminescence in the sample compartment so that the sample is inside the housing in absence of a source of a light from outside of the housing;

a detection assembly inside the housing for detecting the chemiluminescence and generating a signal in response to its detection;

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a transparent window inside the housing between a sample chamber and detection assembly, said transparent window being covered with a conductive transparent coating to minimize the direct injection of static charge; and

a controller inside the housing for determining whether a resulting signal processed in response to the signal generated by the detection assembly is indicative of the presence of the sample; and

an LED mounted in the sample compartment to emit a beam of light projecting through the window and striking a first photodiode which generates a signal, and software executed on the controller for comparing the signal generated by the first photodiode to an LED reference value to provide a calibration value indicative of the cleanliness of the transparent window and accounted for during detection the ~~measurement~~ of the resulting signal.

39. (Currently amended) A hand-held assay device for detecting the presence of a sample ~~selected from the group consisting of ATP and other entity capable of chemically reacting to generate~~ generating chemiluminescence, comprising:

a housing provided with a sample compartment receiving the sample;

a source of light mounted in the housing and emitting a beam of light extending along a path;

a detection assembly along the path for generating a resulting signal in response to the chemiluminescence;

a transparent window along the path between the sample compartment and the detection assembly, the detection assembly generating a calibration signal indicating

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cleanliness of the transparent window in response to being struck by the beam of light from the source; and

a controller having an analytical mode, wherein the resulting signal is evaluated, and a calibration mode, wherein the calibration signal is evaluated.

43. (Currently amended) A hand-held assay device for detecting the presence of a sample ~~selected from the group consisting of ATP and other entity capable of chemically reacting to generate~~ generating chemiluminescence, comprising:

a housing provided with a sample compartment; with a closeable door for enclosing a consumable for collecting the sample and which is removably inserted into the sample compartment of the housing so that the sample and the consumable are inside the housing in the absence of a source of light from outside of the housing when the door is closed;

a detection assembly located in the housing along ~~[[the]]~~ a path and juxtaposed with the consumable upon insertion of the consumable into the sample compartment, the detection assembly generating a resulting signal in response to the chemiluminescence and generating a consumable-present signal in response to detecting the consumable; and

a controller preventing the device from operating further unless a source of light from outside of the housing is absent and having an analytical mode, wherein the resulting signal is evaluated, and a detection mode, wherein the consumable-present signal is evaluated.

46. (Currently amended) The hand-held assay device defined in claim 42, further comprising a source of light mounted in the sample compartment, and software executed

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on the controller for comparing ~~[[the]]~~ a consumable-present signal with high, mid and low level values of an expected intensity of the light from the source of light.

50. (Currently amended) A hand-held assay device for detecting the presence of a sample ~~selected from the group consisting of ATP and other entity capable of chemically reacting to generate~~ generating chemiluminescence, comprising:

a housing provided with a sample compartment;

a consumable adapted to be removably inserted in the sample compartment after collecting the sample, the sample compartment being provided with a transparent bottom;

a source of light provided in the sample compartment and emitting a beam of light which projects through the transparent bottom;

a detection assembly juxtaposed with the transparent bottom for generating a first signal in response to detection of the chemiluminescence and a second signal in response to being struck by the beam of light; and

a controller receiving the first and second signals and having a first mode, wherein the first signal is evaluated to determine the presence of the sample, a second mode, wherein the second signal is evaluated to determine the cleanliness of the transparent bottom, and a third mode, wherein the second signal is determined to be indicative of the presence of the consumable.

56. (Currently amended) The hand-held assay device defined in claim 49 wherein the transparent bottom having opposite sides, one of which is coated with indium tin oxide, ~~[[an]]~~ ITO, to provide a shutterless structure of the hand-held device.

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57.(Currently amended) A method of measuring the presence of a sample ~~selected from the group consisting of ATP and other entity capable of generating~~ chemiluminescence, comprising the steps of:

providing a first photodiode for generating a sample signal in response to detecting the chemiluminescence;

providing a second photodiode shielded from the chemiluminescence for generating a reference signal;

providing a closeable door allowing access to a sample compartment containing the sample in the absence of a source of light from outside of the sample compartment when the door is closed;

providing a controller receiving the sample signal and reference signal for preventing further operation in response to light from outside of the housing as determined by software executed on the controller which generates a warning signal in response to the detection of the light indicative of an open door, and subtracting the reference signal from the sample signal to determine a resulting signal; and

comparing the resulting signal with a predetermined threshold signal; and

displaying the resulting signal indicative of the sample if the resulting signal is at least equal to the threshold value.

58.(Currently amended) A method for detecting the presence of a sample ~~selected from the group consisting of ATP and other entity capable of chemically reacting to generate~~ generating chemiluminescence, comprising the steps of:

providing a housing having a sample compartment formed with a transparent bottom;

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providing a closeable door allowing access to the sample compartment containing the sample in the absence of a source of light from outside of the sample compartment when the door is closed;

activating a source of light in the sample compartment;

generating a resulting signal from the source of light;

continuing ~~[[the]]~~ detection procedure if the resulting signal does not exceed a level expected of a test signal when there is an absence of a source of light from outside of the housing;

detecting the chemiluminescence and generating a signal in response to the detection;

providing a film of a conductive ~~plastic~~ material on the transparent bottom, thereby minimizing the direct injection of static charge; and

comparing the signal with a predetermined threshold; and

displaying a value of the signal if the signal is at least equal to the predetermined threshold.

59. (Currently amended) A method for detecting the presence of a sample ~~selected from the group consisting of ATP and other entity capable of chemically reacting to generate~~ generating chemiluminescence, said sample being placed in a sample compartment provided in a housing, comprising the steps of:

providing a closeable door allowing access to the sample compartment containing the sample in the absence of a source of light from outside of the sample compartment when the door is closed;

activating a source of light in the sample compartment;

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generating a resulting signal from the source of light;

continuing ~~[[the]] detection procedure~~ if the resulting signal does not exceed a level expected of a test signal when there is an absence of a source of light from outside of the housing;

generating a sample signal in response to detecting the chemiluminescence;

generating a reference signal in response to detecting environmental changes selected from the group consisting of humidity, temperature drifts and a combination thereof;

integrating the sample and reference signals during a controllable integration period to produce integrated values of the sample and reference signals;

digitizing the integrated values of the sample and reference signals;

subtracting the digitized value of the reference signal from the digitized value of the sample signal to determine a value of a resulting signal;

comparing the value of the resulting signal with a predetermined threshold and displaying the resulting signal indicative of the presence of the sample if the value of the resulting signal is at least equal to the threshold.

62. (Currently amended) A method for detecting the presence of a sample selected ~~from the group consisting of ATP and other entity capable of chemically reacting to generate~~ generating chemiluminescence, said sample being placed in a sample compartment provided in a housing, comprising the steps of:

generating a sample signal in response to detecting the chemiluminescence;

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generating a reference signal in response to detecting environmental changes selected from the group consisting of humidity, temperature drifts and a combination thereof;

integrating the sample and reference signals during a controllable integration period to produce integrated values of the sample and reference signals;

digitizing the integrated values of the sample and reference signals;

subtracting the digitized value of the reference signal from the digitized value of the sample signal to determine a value of a resulting signal;

comparing the value of the resulting signal with a predetermined threshold and displaying the resulting signal indicative of the presence of the sample if the value of the resulting signal is at least equal to the threshold; and

determining the cleanliness of the transparent bottom before determining the resulting signal.

Allowable Subject Matter

2. **Claims 1-62** are allowed.

As to **claim 1**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a hand held device the particular software and particular controller for determining light outside of the housing, in combination with the rest of the limitations of **claims 1-5, 7, 8, 12, 15-22**.

As to **claim 6**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a hand held device the particular software, in combination with the rest of the limitations of **claim 6**.

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As to **claim 9**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a handheld device “a calibration mode, wherein the cleanliness of the window is controlled” in combination with the rest of the limitations of **claim 9-11; 23-27**.

As to **claim 13**, the prior art of record, taken alone or in combination, fails to disclose or render obvious a hand held assay device, “a LED pressed into a peripheral wall of the sample compartment” in combination with the rest of the limitations of **claims 13-14**.

As to **claim 28**, the prior art of record, taken alone or in combination, fails to disclose or render obvious a hand held assay device, a window covered with an electro-conductive plastic in electrical contact with the chassis, and having a filter which is a bandpass filter or a band-limited filter in combination with the rest of the limitations of **claim 28**.

As to **claim 29**, the prior art of record, taken alone or in combination, fails to disclose or render obvious a hand held assay device, software for determining the presence of holes in the door in combination with the rest of the limitations of **claim 29**.

As to **claim 30**, the prior art of record, taken alone or in combination, fails to disclose or render obvious a hand held assay device, software for preventing device from operating if the light outside the housing is present in combination with the rest of the limitations of **claim 30**.

As to **claim 34**, the prior art of record, taken alone or in combination, fails to disclose or render obvious handheld assay device “a bandpass filter” in combination with the rest of the limitations of **claim 34**.

As to **claim 35**, the prior art of record, taken alone or in combination, fails to disclose or render obvious handheld assay device “a bandpass filter” in combination with the rest of the limitations of **claim 35**.

As to **claim 36**, the prior art of record, taken alone or in combination, fails to disclose or render obvious handheld assay device “a calibration value indicative of the cleanliness of the transparent window” in combination with the rest of the limitations of **claim 36**.

As to **claim 39**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a handheld device “the detection assembly generating a calibration signal indicating cleanliness of the transparent window” in combination with the rest of the limitations of **claims 39-42, 44-49, and 51-56**.

As to **claim 43**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a handheld device “a controller preventing the device from operating further unless light outside of the housing is absent” in combination with the rest of the limitations of **claim 43**.

As to **claim 50**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a handheld assay device the first, second, and third modes, in combination with the rest of the limitations of **claim 50**.

As to **claim 57**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a method of measuring the presence of a sample the particular providing a controller step in combination with the rest of the limitations of **claim 57**.

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As to **claim 58**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a method of measuring the presence of a sample the particular continuing step in combination with the rest of the limitations of **claim 58**.

As to **claim 59**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a method of measuring the presence of a sample the particular continuing step in combination with the rest of the limitations of **claim 59**.

As to **claim 62**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in a method of measuring the presence of a sample “the step of determining the cleanliness of the transparent bottom before determining the resulting signal” in combination with the rest of the limitations of **claim 62**.

Response to Arguments

3. Applicant's arguments, see Remarks, filed January 24, 2005 with respect to the rejections under 35 U.S.C. 103(a) and 35 U.S.C. 112 first paragraph of the previous action have been fully considered and are persuasive. Due the persuasiveness of the arguments and the amendment of the claims, the previous rejections have been withdrawn.

Fax/Telephone Numbers

If the applicant wishes to send a fax dealing with either a proposed amendment or a discussion with a phone interview, then the fax should:

- 1) Contain either a statement “DRAFT” or “PROPOSED AMENDMENT” on the fax cover sheet; and
- 2) Should be unsigned by the attorney or agent.

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This will ensure that it will not be entered into the case and will be forwarded to the examiner as quickly as possible.

Papers related to the application may be submitted to Group 2800 by Fax transmission. Papers should be faxed to Group 2800 via the PTO Fax machine located in Crystal Plaza 4. The form of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CP4 Fax Machine number is: (703) 872-9306

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gordon J. Stock whose telephone number is (571) 272-2431.

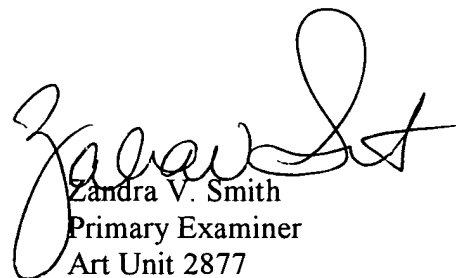
The examiner can normally be reached on Monday-Friday, 10:00 a.m. - 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory J. Toatley, Jr., can be reached at 571-272-2800 ext 77.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



gs
March 1, 2005



Zandra V. Smith
Primary Examiner
Art Unit 2877